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## **Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment**

Wilkoff, B L ; Bello, D ; Taborsky, M ; Vymazal, J ; Kanal, E ; Heuer, H ; Hecking, K ; Johnson, W B ;  
Young, W ; Ramza, B ; Akhtar, N ; Kuepper, B ; Hunold, P ; Luechinger, R ; Puererfellner, H ; Duru,  
F ; Gotte, M J W ; Sutton, R ; Sommer, T

**Abstract:** Background Magnetic resonance imaging (MRI) of pacemaker patients is contraindicated due to documented potential risks to the patient from hazardous interactions between the MRI and pacemaker system. Objective The purpose of this prospective, randomized, controlled, worldwide clinical trial was to evaluate the safety and effectiveness of a pacemaker system designed for safe use in MRI for any bradycardia indicated patient. Methods Patients (n = 464) were randomized to undergo an MRI scan between 9 and 12 weeks postimplant (MRI group, n = 258) or not to undergo MRI (control group, n = 206) after successful implantation of the specially designed dual-chamber pacemaker and leads. Patients were monitored for arrhythmias, symptoms, and pacemaker system function during 14 nonclinically indicated relevant brain and lumbar MRI sequences. Sequences were performed at 1.5 T and included scans with high radiofrequency power deposition and/or high gradient dB/dt exposure. Clinical evaluation of the pacemaker system function occurred immediately before and after MRI, 1 week and 1 month post-MRI, and at corresponding times for the control group. Primary endpoints for safety analyzed the MRI procedure complication-free rate and for effectiveness compared capture and sensing performance between MRI and control groups. Results No MRI-related complications occurred during or after MRI, including sustained ventricular arrhythmias, pacemaker inhibition or output failures, electrical resets, or other pacemaker malfunctions. Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups. Conclusion This trial documented the ability of this pacemaker system to be exposed in a controlled fashion to MRI in a 1.5 T scanner without adverse impact on patient outcomes or pacemaker system function.

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# Magnetic Resonance Imaging in Patients with a Pacemaker System Designed for the MR Environment

## **MRI WITH A PACEMAKER SYSTEM DESIGNED FOR THE MR ENVIRONMENT**

Authors: Bruce L. Wilkoff<sup>1</sup>, David Bello<sup>2</sup>, Milos Taborsky<sup>3</sup>, Josef Vymazal<sup>3</sup>, Emanuel Kanal<sup>4</sup>, Hubertus Heuer<sup>5</sup>, Katrin Hecking<sup>5</sup>, W. Ben Johnson<sup>6</sup>, William Young<sup>6</sup>, Brian Ramza<sup>7</sup>, Naveed Akhtar<sup>7</sup>, Bernhard Kuepper<sup>8</sup>, Peter Hunold<sup>8</sup>, Roger Luechinger<sup>9</sup>, Helmut Puererfellner<sup>10</sup>, Firat Duru<sup>11</sup>, M.J.W.Gotte<sup>12</sup>, Richard Sutton<sup>13</sup>, Torsten Sommer<sup>14</sup>  
on behalf of the EnRhythm MRI SureScan Pacing System Study Investigators

### **Funding**

Medtronic, Inc. provided funding for this trial, and is the manufacturer of the dual-chamber pacemaker system used in the trial.

### **Conflict of Interest**

The following persons are consultants to Medtronic:

Bruce L. Wilkoff, David Bello, Emanuel Kanal, W. Ben Johnson, Brian Ramza, Roger Luechinger, Helmut Puererfellner, Firat Duru, Richard Sutton, and Torsten Sommer.

### **Author Justification**

Each author has participated sufficiently in the work by 1) provided substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and 2) drafted manuscript or revised for intellectual content.

Address for correspondence:

<sup>1</sup> Cleveland Clinic, J2-2, 9500 Euclid Ave, Cleveland, OH 44195, US, wilkoff@ccf.org

<sup>2</sup> Orlando Regional Medical Center, 1717 South Orange Avenue #105, Orlando, FL 32806, US, bello@mid-florida-cardiology.com

<sup>3</sup> Na Homolce Hospital, Roentgenova 2, 15030, Prague 5, Czech Republic, milos.taborsky@homolka.cz and Josef.Vymazal@homolka.cz

<sup>4</sup> UPMC Presbyterian, 200 Lothrop Street, Pittsburgh, PA 15213, US, ekanal@pitt.edu

<sup>5</sup> St. Johannes Hospital, Johannesstraße 9 – 13, 44137 Dortmund, Germany, heuer@joho-dortmund.de and katrin.hecking@joho-dortmund.de

- <sup>6</sup> Iowa Heart Center P.C./Mercy Hospital, 411 Laurel Street, Des Moines, IA 50314, US, [wjohnson@iowaheart.com](mailto:wjohnson@iowaheart.com) and [wyoung@mercydesmoines.org](mailto:wyoung@mercydesmoines.org)
- <sup>7</sup> Mid America Heart Institute, 4330 Wornall Road, Kansas City, MO 64111, US, [bramza@cc-pc.com](mailto:bramza@cc-pc.com) and [makhtar@saint-lukes.org](mailto:makhtar@saint-lukes.org)
- <sup>8</sup> Elisabeth Krankenhaus, Klara-Kopp-Weg 1, 45138 Essen, Germany, [b.kuepper@elisabeth-essen.de](mailto:b.kuepper@elisabeth-essen.de) and [peter.hunold@uk-sh.de](mailto:peter.hunold@uk-sh.de)
- <sup>9</sup> Institute for Biomedical Engineering, University and ETH Zurich, Gloriastrasse 35, 8092 Zurich, Switzerland, [luechinger@biomed.ee.ethz.ch](mailto:luechinger@biomed.ee.ethz.ch)
- <sup>10</sup> A.ö. Krankenhaus der Elisabethinen, Fadingerstrasse 1, 4010 Linz, Austria, [helmut.puererfellner@elisabethinen.or.at](mailto:helmut.puererfellner@elisabethinen.or.at)
- <sup>11</sup> University Hospital Zurich, Rämistrasse 100, 8091 Zurich, Switzerland, [fiat.duru@usz.ch](mailto:fiat.duru@usz.ch)
- <sup>12</sup> Haga Ziekenhuis, Locatie Leyweg, Leyweg 275, 2545 CH Den Haag, The Netherlands, [mjw.gotte@hagaziekenhuis.nl](mailto:mjw.gotte@hagaziekenhuis.nl)
- <sup>13</sup> St. Mary's Hospital, Praed Street, W2 1NY London, United Kingdom, [r.sutton@imperial.ac.uk](mailto:r.sutton@imperial.ac.uk)
- <sup>14</sup> German Red Cross Hospital (DRK) Neuwied, Academic Hospital of the University of Bonn, Marktstr. 104, D-56564 Neuwied, Germany, [torsten.sommer@drk-kh-neuwied.de](mailto:torsten.sommer@drk-kh-neuwied.de)

## Abstract and Keywords

**Background:** Magnetic Resonance Imaging (MRI) of pacemaker patients is contraindicated due to documented potential risks to the patient from hazardous interactions between the MRI and pacemaker system.

**Objective:** This prospective, randomized controlled, worldwide clinical trial evaluated safety and effectiveness of a pacemaker system designed for safe use in MRI for any bradycardia indicated patient.

**Method:** Patients (n=464) were randomized to undergo an MRI scan between 9-12 weeks post-implant (MRI group, n=258) or not to undergo MRI (control group, n=206) after successful implantation of the specially designed dual chamber pacemaker and leads. Patients were monitored for arrhythmias, symptoms and pacemaker system function during 14 non clinically indicated relevant brain and lumbar MRI sequences. Sequences were performed at 1.5 Tesla (T) and included scans with high radiofrequency power deposition and/or high gradient dB/dt exposure. Clinical evaluation of the pacemaker system function occurred immediately before and after MRI, 1-week and 1-month post-MRI and at corresponding times for the control group. Primary endpoints for safety analyzed the MRI procedure complication-free rate, and for effectiveness compared capture and sensing performance between MRI and control groups.

**Results:** No MRI-related complications occurred during or after MRI, including sustained ventricular arrhythmias, pacemaker inhibition or output failures, electrical

resets or other pacemaker malfunctions. Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups.

**Conclusion:** This trial documented the pacemaker system's ability to be exposed in a controlled fashion to MRI in a 1.5T scanner without adverse impact on patient outcomes or pacemaker system function.

**Keywords:** Bradycardia pacing, CapsureFix MRI™ Model 5086MRI, EnRhythm MRI™, MRI, Safety, SureScan™, Pacemaker, Revo MRI™

## **List of abbreviations**

CI	Confidence Interval
ICD	Implantable Cardioverter Defibrillator
IPG	Implantable Pulse Generator
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PCT	Pacing Capture Threshold
RF	Radio Frequency
SAR	Specific Absorption Rate
ACLS	Advanced Cardiovascular Life Support

## **Introduction**

### ***Safe Access to MRI is a Critical Need for Pacemaker Patients***

The use of Magnetic Resonance Imaging (MRI) as the imaging modality of choice in many fields (e.g. brain, spinal cord and musculoskeletal system) is rapidly increasing. However, manufacturers of cardiac devices and of MRI systems contraindicate MRI for patients with implanted pacemaker systems due to multiple associated risks. Approximately 5,000,000 patients worldwide are currently implanted with a pacemaker or implantable cardioverter defibrillator (ICD) and at least 50% of these patients are expected to be indicated to undergo clinical MRI over the lifetime of their device.<sup>1</sup>

### ***Risks associated with MRI scans of pacemaker patients***

Literature documents that there are several interactions between the MRI associated static magnetic field, gradient fields and radiofrequency (RF) field and the implanted pacemaker system may be hazardous to the patient and/or damage the device.<sup>2-4</sup> Despite the potential for adverse outcomes, a few centers perform MRI scanning of carefully selected pacemaker patients using precautions when the benefit outweighs the risk. Even in these centers and under extensive expert supervision, clinically significant irregular pacemaker system behavior cannot always be prevented or good patient outcomes assured.<sup>5</sup>

A pacemaker system (EnRhythm MRI™ SureScan™ Implantable Pulse Generator (IPG) and CapSureFix MRI™ leads (Model 5086MRI leads) used in support for Revo MRI SureScan pacing system, Medtronic, Inc., Minneapolis, MN) designed specifically

to mitigate these hazards provides access to pacemaker patients for this important diagnostic modality. The aim of the trial was to evaluate safety and efficacy of this novel pacemaker system during MRI in a prospective, randomized, multicenter trial.

## **Methods**

### ***Pacemaker system***

The following design modifications were made to the pacemaker system to improve MRI compatibility: 1) The leads were modified to reduce RF lead tip heating, 2) Internal circuits were changed to reduce the potential for cardiac stimulation, 3) The amount of ferromagnetic materials was limited, 4) Internal circuit protection was improved to prevent disruption of the internal power supply, 5) The reed switch was replaced by a Hall sensor, whose behavior in a static magnetic field is predictable and 6) A dedicated programming care pathway was developed to facilitate the choice between asynchronous versus non-stimulation modes, increase the pacing output to 5.0V / 1.0 ms during MRI scanning, prevent programming the MRI mode if the device fails any of the 10 system integrity checks and facilitate restoration of pre-scan program states and values. (Table 1)

Conditions for safely scanning patients with this system during this trial required a static magnetic field strength of 1.5T, a maximum Specific Absorption Rate (SAR) value of 2W/kg for each sequence and a maximum gradient slew rate of 200T/m/s.

Furthermore, the position of the isocenter of the RF transmitter coil must be above the superior surface of the C1 vertebra or below the inferior surface of the body of T12.



### ***Trial design and patient selection***

This was a prospective, randomized controlled, multicenter clinical trial with centers in the United States, Canada, Europe and the Middle East (ClinicalTrials.gov identifier NCT00433654).<sup>6</sup> The trial was performed in accordance with the Declaration of Helsinki and to laws and regulations of the countries which participated. Each center had Medical Ethics Committee approval of the trial protocol and each patient had written informed consent prior to enrollment. Patients were enrolled who met Class I or II dual chamber pacemaker implant indications according to ACC/AHA/HRS guidelines<sup>7</sup> (either pacemaker dependent or non-pacemaker dependent) and were able and willing to undergo a non clinically indicated MRI scan without intravenous sedation, had no implanted non-MRI compatible devices or materials, no other implantable active medical devices and no abandoned leads.

### ***Data collection and analysis***

After a successful pacemaker and lead implantation, randomization was performed to either undergo an MRI scan (MRI group) or not to undergo an MRI scan (Control) at 9-12 weeks after system implantation. Initially patients were randomized 1:1 but later changed to 2:1 to meet the regulatory requirement for >200 scanned patients. Follow-up visits are summarized in Figure 1. The 9-12 week visit consisted of an evaluation immediately before (pre-MRI evaluation), during (MRI) and directly after the MRI (post-MRI evaluation) as well at the corresponding time points for the control group. During these evaluations, pacemaker performance, including assessment of pacing capture threshold (PCT) at a pulse duration of 0.5ms, sensed electrogram amplitude and lead impedance, were performed. Technical observations and adverse events were evaluated,

including sustained ventricular arrhythmias, pacemaker output inhibition, asystole, electrical reset, and pacemaker function during and after the MRI scan. Data stored within the pacemaker, rhythm strips during PCT testing and case report forms were collected.

### ***MRI***

The MRI scans were performed with 1.5T systems from three MRI manufacturers (General Electric, Philips and Siemens). The body coil served as the RF transmit coil. Fourteen MRI head and lumbar spine sequences were performed. Total MRI investigation time was approximately 60 minutes (static magnetic field exposure) with a total active MRI scanning time of approximately 30 minutes (gradient and RF field exposure). MRI scanning protocol represented clinically relevant scans with a maximized gradient slew rate up to 200T/m/s and/or a maximized transmitted RF power up to SAR levels of 2W/kg body weight (upper limit of normal operating mode). Due to the MRI interference, electrocardiographic monitoring provided inaccurate assessments of heart rate and rhythm. Instead, pulse oximetry provided the ability to continuously monitor heart rate and oxygen saturation and was not affected by the MRI fields. Patients were also monitored using verbal communication and when available, non-invasive blood pressure monitoring.

### ***Statistics***

To assess if the MRI related complication-free rate in the month following the MRI was greater than 90%, a one-sided one-sample exact test of binomial proportions along with a one-sided 97.5% confidence interval (CI) were calculated.

The proportion of patients who experienced a change in PCT of  $\leq 0.5V$  at 0.5ms from before the MRI/control visit to the 1-month post visit were tested for equivalence between MRI and control groups by using a two-sample 97.5% confidence interval, with Farrington-Manning p-values. The equivalence margin was 10%. The proportion of patients who experienced a change in sensing amplitudes from before the MRI/control visit to the 1-month post visit were tested for statistical equivalence between the MRI and control group by two-sample one-sided 97.5% CI, with p-values from the Farrington-Manning test for equivalence of proportions. Success was achieved if the sensing amplitude decreased less than or equal to 50% and the amplitude remained above a clinically acceptable minimum of 1.5mV in the atrium or 5.0mV in the ventricle.

Pre-specified analysis exclusion criteria were listed in the protocol. Additional analyses were performed to include excluded data from the PCT and sensing analyses.

The proportion of patients free of system-related complications related from implant until 1-month post-MRI/control visit was compared to a value of 80% by a one-sided one-sample exact test with one-sided 95% CI.

Statistics were performed by Medtronic and re-evaluated by the Cleveland Clinic Coordinating Center for Clinical Research (C5 Research), Cleveland, OH, US.

### ***Adverse Event Classification***

All adverse events were classified in several ways by an adverse events committee: according to their relationship to the implant procedure, to the MR procedure, and to the pacing system. In some cases, adverse events were classified as having an unclear relationship to the implant, MR or pacing system due to the inability to assign the

component of the system or procedure. In addition, adverse events were classified as either complications or observations. The definition of a complication was predefined as an adverse event that resulted in an invasive intervention or the termination of significant device function. The definition of an observation was predefined as an adverse event that was not a complication.

Independent data monitoring, MRI scan advisory, and adverse events committees reviewed information and provided recommendations.

## Results

### *Trial population*

A total of 464 patients were randomized after successful pacemaker system implantation between February 2007 and August 2008 (258 to the MRI group and 206 to the control group). A summary of the distribution of patient enrollments, follow-up by randomized group, and inclusion and exclusion of data are listed in Figure 1. The mean follow-up time was  $11.2 \pm 5.2$  months (range 0.1-21.5 months). The patient characteristics were typical of pacemaker patients and are listed in Table 2 **Error! Reference source not found..**

### *Safety*

A total of 211 patients had an MRI performed per protocol instructions and completed the 1-month post-MRI/control visit. There were no MRI-related complications through the 1-month post-MRI/control visit and thus the proportion of patients free of MRI-related complications was 100% (211/211), with a one-sided 97.5% CI of 98.3%. When analyzed

against the comparison rate of 90%, the p-value is <0.001. In addition, none of the additional 16 patients who underwent any portion of the MRI scan: partial scan (n=6), exceeded maximum allowed SAR scan limits (n=8), exceeded pre-MRI evaluation capture threshold (high capture threshold, n=1), or control patient who inadvertently underwent an MRI scan (n=1), experienced MRI-related complications.

All MRI examinations (226/226, 100%, 95% CI 98.7-100%) were completed safely with continuous pacemaker stimulation when programmed to asynchronous mode (n=158), or regular spontaneous intrinsic activation when programmed to no pacing mode (n=67). One subject was scanned in an unknown mode. Formal assessment of pacemaker dependency was not evaluated however 16 MRI and 11 control patients had no ventricular intrinsic rhythm at the pre 9-12 week assessment. No inhibition of pacemaker output, asystole, sustained ventricular arrhythmias, unexpected changes of heart rate, or electrical resets occurred during MRI. No pacemaker system disturbances during or after MRI were observed. No sensation of torque or pain was reported during MRI.

While there were no MRI complications, there were eight observations which were either classified as being MRI related or unclear if related to the MRI procedure. Four patients reported paraesthesia (n=3) and palpitation symptoms (n=1), which were identified as related to the MRI, required no invasive actions and all resolved the same day as the MRI. These events are typical events seen among patients who receive MRIs. Another four patients reported mild transient chest pressure (n=1), swallowing problems (n=1), atrial flutter (n=1) and atrial fibrillation symptoms (n=1), which were assessed as having an unknown relationship to the MRI, but no relationship to the pacemaker system and required no invasive interventions.

Over the course of the trial eleven deaths occurred, including nine in the MRI group. None were related to the MRI procedure, implantation procedure or pacemaker system. Three deaths occurred prior to the MRI exam, and six deaths occurred after the MRI exam (pulmonary edema related to renal failure, non-cardiac sepsis, myocardial infarction, stroke, acute ischemic stroke and cardiac failure occurred 10, 43, 193, 299, 402 and 461 days after the MRI procedure, respectively). The discrepancy between MRI and control deaths appears to be a statistical variant, with no clear relationship of mode of death.

The proportion of patients free of pacemaker system-related complications through the 1-month post-MRI/control visit was expected to be greater than 80% and was measured to be 91.7% (410/447), with a one-sided 95% CI of 89.3% ( $p < 0.001$ ). A total of 37 patients experienced 43 system-related complications exhibited as lead dislodgement ( $n=17$ ), elevated capture thresholds ( $n=9$ ), pericardial effusion ( $n=3$ ) and failure to capture ( $n=3$ ). None of these were related to MRI.

### ***Pacing capture threshold equivalence***

The proportions of patients in the MRI and control group who experienced an increase in  $PCT \leq 0.5V$  from directly before the MRI/control visit to the 1-month post visit were clinically and statistically equivalent. None of the atrial (165/165, MRI vs. 164/164, control) or ventricular lead (190/190, MRI vs. 183/184, control) PCT patients demonstrated an increase of  $>0.5 V$  and only one of the ventricular control patients increased 1.0 V. PCT was 5 V prior to and 6V one-month after the 9-12 week control evaluations and the lead was subsequently replaced. With both atrial capture success rates at 100%, the one-sided 97.5% confidence bound could not be calculated. The upper

bound of the one-sided 97.5% confidence limit was 1.6% for the ventricular PCT changes ( $p \leq 0.001$ ), indicating that the two groups are statistically comparable. (Figure 2&3)

The intention to treat analysis included data from MRI scan deviations, late follow-up visits, and all available follow-up visits, the atrial threshold success rates were 200/200 in the MRI group (100%) and 177/177 (100%) in the control group. The ventricular threshold success rates were 224/225 in the MRI group (99.6%) and 194/195 (99.5%) in the control group. In one patient, the PCT increased from 1.5V before the MRI to 2V immediately after the MRI and to 2.5V at 1-month post-MRI visit. In this patient PCT returned to 2V at the 12-month visit. Also in this patient the SAR limit of 2 W/kg was exceeded for one lumbar scan sequence (2.5W/kg) when performing the full set of brain and lumbar scans, the only such instance in the eight patients in whom the SAR limit was exceeded. The upper bound of the one-sided 97.5% confidence limit was 1.4%. This additional analysis supported that the PCT success rates of the two groups were equivalent.

### ***Sensing equivalence***

There was clinical equivalence of the proportion of patients who maintained the sensed electrogram amplitudes above 1.5mV (atrial) or 5mV (ventricle) at 1-month post MRI/control visit and above 50% of the amplitude measured directly before the MRI/control visit as compared to the 1-month post-MRI/ control evaluation. The success rate for atrial sensing amplitude was 94.7% (124/131) in the MRI group and 92.8% (129/139) in the control group. The success rate for ventricular sensing amplitude was 97.0% (130/134) in the MRI group and 94.9% (129/136) in the control group. Sensing values below the 1.5mV (atrial) or 5.0mV (ventricle) at the 1-month post-MRI/control

visit were primarily the reasons for non-success. The upper bounds of the one-sided 97.5% confidence limits were 7.6% ( $p \leq 0.001$ ) for the atrial and 6.9% ( $p \leq 0.001$ ) for the ventricle sensing amplitudes, indicating that the two groups are statistically comparable. (Figure 4)

By intention to treat analysis, the success rates for atrial sensing amplitudes were 162/172 in the MRI group (94.2%) and 141/151 (93.4%) in the control group. The upper bound of the one-sided 97.5% confidence limit was 6.1%. The ventricular sensing success rates were 172/178 in the MRI group (96.6%) and 140/147 (95.2%) in the control group. The upper bound of the one-sided 97.5% confidence limit was 5.7%. In addition, all subjects with low sensing values ( $<1.5\text{mV}$  for atrial and  $<5.0\text{mV}$  for ventricular) just before the MRI/control visit were considered successful because the sensing amplitude decrease did not exceed 50%. These additional analyses supported that the sensing amplitude success rates of the two groups were comparable.

### ***Impedance equivalence***

The impedance results did not exhibit change beyond expected variations with repeated measurements. (Figure 5)

## **Discussion**

This prospective, randomized controlled, multicenter trial evaluated safety and efficacy of a pacemaker system specifically designed to be used during MRI. No MRI-related complications, no disturbances of pacemaker function, and no ventricular arrhythmia induction were observed. PCT and sensing amplitude changes from immediately before



the MRI/control visit to the 1-month post visit were clinically equivalent between MRI and control groups. All pacemaker system-related complications were within an expected and clinically acceptable range.<sup>8-10</sup> These results indicate that this pacemaker system can be used safely in an MRI environment when used in accordance with its labeling.

### ***RF-induced heating***

Heating of pacemaker leads during MRI has been shown to depend on numerous parameters including the amount of transmitted RF energy (quantified by the SAR), patient size and anatomy, patient position within the scanner bore, and the position of the pacemaker lead within the RF field.<sup>11-14</sup> Furthermore, heating depends on the specific lead design and lead length. Variations among different lead models can result in different risks of lead tip heating.<sup>15</sup>

Publications have shown that substantial increases in PCT<sup>16, 17</sup> and serum troponin<sup>16</sup> can be observed after MRI at 1.5T in patients implanted with conventional pacemakers. PCT changes have been attributed to RF-induced heating of the cardiac tissue in proximity to the pacemaker lead tip, resulting in thermal injury.<sup>16</sup> These findings of potential RF-related thermal injury are further supported by in-vitro experiments<sup>4, 18, 19</sup> and in-vivo animal studies.<sup>3, 4</sup>

The leads of this new pacemaker system were modified to reduce lead tip heating from transmitted RF power. To be conservative and further minimize heating when performing an MRI scan with this new pacemaker system, centering the transmitting RF coil between C1 and T12 was precluded and the SAR value was restricted to  $\leq 2\text{W/kg}$ . It should be noted that the positioning restriction (isocenter of the coil to a position outside

the area of the superior surface of C1 vertebra to the inferior surface of T12 vertebra) still permits scanning the complete cervical region and most, if not all, of the thoracic region by widening the field of view. The SAR value of  $\leq 2\text{W/kg}$  is the upper limit of the Normal Operating Mode, which allows performance of the vast majority of clinically relevant MRI scans.

There was clinical equivalence for the proportions of patients in the MRI and control group who experienced PCT or sensing amplitude changes from directly before to 1-month post-MRI/control visit. This is consistent with a lack of clinically relevant RF-induced myocardial thermal damage induced by MRI in patients with this pacemaker system.

### ***Unintended Cardiac Stimulation***

Gradient magnetic and RF electromagnetic fields produced by MRI scanners induce pulsed voltages in pacemaker leads that are conducted to the heart at the myocardial-electrode interface. If these MRI-induced voltage pulses are large enough, they could directly stimulate the heart, which is known as unintended cardiac stimulation (UCS). Clinical manifestations of UCS due to single or multiple captured beats include palpitations or hemodynamic collapse and potentially fatal sustained ventricular tachycardia. Out of 227 patients exposed to the MRI scanning protocol who were monitored via pulse oximetry, there were no UCS adverse events reported with relationship to the MRI procedure.

### ***Interference with pacemaker function***

In the strong static magnetic field of the MRI unit, the reed switch state (open or closed) and the pacemaker (synchronous or asynchronous) is not always predictable.<sup>20</sup> If the pacemaker stays in synchronous mode during an MRI examination, the gradient field can mimic intrinsic cardiac electrical activity, and, thus, inhibit pacemaker output<sup>21</sup>, which may be fatal for a pacemaker-dependent patient. On the other hand, fixed cardiac pacing in an asynchronous mode due to MRI-related closure of the reed switch may lead to competitive rhythms (intrinsic rhythm and fixed pacemaker stimulation), creating a risk of inducing possibly fatal tachyarrhythmias.<sup>22, 23</sup>

The use of a Hall sensor mitigates this risk, whose behavior in the MRI environment is predictable, and by including a specific MRI operation feature. With this feature, the Hall sensor is suspended and is not influenced by the static magnetic field; the physician can

choose either to program the pacemaker to an asynchronous pacing mode or to a non-pacing mode. Asynchronous pacing will maintain appropriate pacing support throughout the MRI examination regardless of the noise sensed by the pacemaker system and without the risk of pacing output inhibition. For patients who are non-pacemaker dependent, the non-pacing mode is available.

### ***Electrical Reset***

An electrical reset is an emergency safety feature that guarantees minimal pacemaker functionality in case of battery voltage dips due to electromagnetic interference or battery depletion. An electrical reset will cause a change in the programmed parameters to basic settings, and to an inhibited pacing mode (VVI) with a manufacturer determined stimulation rate.

Previously, electrical reset has been reported on exposure to the MRI field in six percent of pacemaker patients undergoing MRI.<sup>16</sup> An electrical reset has important safety implications: 1) When the reed switch remains open pacemaker inhibition potentially leading to bradycardia/asystole 2) When the reed switch is closed by the MRI, competitive rhythms (fixed pacemaker stimulation in asynchronous mode and intrinsic rhythm) may occur with the risk of inducing fatal tachyarrhythmias.

The risk of electrical reset is minimized in the new system by reducing MRI induced voltage on the leads and improving internal circuit protection. Even in the theoretical case of an electrical reset, an additional safety feature maintains the programmed parameter and re-establishes the MRI feature. If programmed parameters can not be maintained following a second electrical reset, it will provide asynchronous pacing.

### ***Comparison with conventional pacemakers used off-label***

It is notable that in previous studies<sup>5,16</sup> that performed MRI scans on patients with conventional pacemakers in off-label use, cardiac myocardial injury, as indicated by increases in PCT and troponin I levels, was not entirely eliminated, even with strict precautionary measures to minimize the risk of RF lead heating. This trial showed only one increase in PCT from pre- to post-MRI/control visit (control group) >0.5V out of 425 leads (0.2%) compared with 6 PCT increases out of 195 leads (3.1%)<sup>16</sup> and 10 PCT increases out of 107 leads (9.4%)<sup>5</sup> in recent major studies. Furthermore, there were no observations of any MRI-induced electrical reset compared with 6% in a previous study<sup>16</sup> using conventional pacemakers. Therefore, these specific pulse generator, software and lead design changes decrease RF-induced heating and risk of electrical resets due to electromagnetic interference, and increase safety for pacemaker patients during MRI scanning.

### ***Limitations***

Use of MRI scanners on pacemaker patients was specifically limited to well-defined conditions in the trial and safe use outside of these conditions has not been demonstrated. Although there was no indicator of misbehavior of the pacemaker and MRI systems, this trial demonstrated safety and efficacy of the device, but did not have the power to look at more rare safety events and does not supplant the need for post market surveillance to detect unexpected or more rare adverse events. Finally, tools for monitoring patients in the MRI environment precluded a specific evaluation of the electrocardiographic rhythm during the MR scan, but visual and verbal monitoring along with pulse oximetry and non

invasive blood pressure monitoring were adequate to assess both the pulse rate and the overall well being of the patient.

## **Conclusion**

MRI scanning of patients with this specific pacemaker system which was evaluated in the trial was performed safely with no adverse impact on either the patient or the pacemaker system. It is important to note that this safety is conditional upon the use of only this complete pacemaker system. Safety is also conditional upon the pacing system being evaluated to assure normal function and appropriate programming, as well as upon following specific limitations on the MR scan, including use in a 1.5T MRI scanner and specific scan protocols. This system designed for use in the MRI environment is expected to safely facilitate access by pacemaker patients to an increasingly important imaging modality.

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**Table 1: Pacing System Integrity Checks**

Pacemaker and both leads implanted > 6 weeks
Pectoral implantation
No other active pacing or ICD devices or leads
No abandoned leads, lead extenders or adapters
Leads electrically intact and with stable and normal function
Lead impedance between 200-1500 ohms
Capture threshold <2.0V at 0.4 ms

**Table 2: Baseline Clinical Characteristics**

Demographic	MRI Group (n=258)	Control Group (n=206)
Age at Implant Mean $\pm$ SD Range	69.3 $\pm$ 12.9 27.8-95.4	68.0 $\pm$ 12.6 19.2-87.3
Male Female	154 (59.7%) 104 (40.3%)	135 (65.5%) 71 (34.5%)
Primary indication for implant AV block Sinus node dysfunction Other	95 (36.8%) 122 (47.3%) 41 (15.9%)	84 (40.8%) 90 (43.7%) 32 (15.5%)
Atrial Fibrillation/Atrial Flutter/Atrial Tachycardia	130 (50.4%)	82 (39.8%)

## **Figures and Legends:**

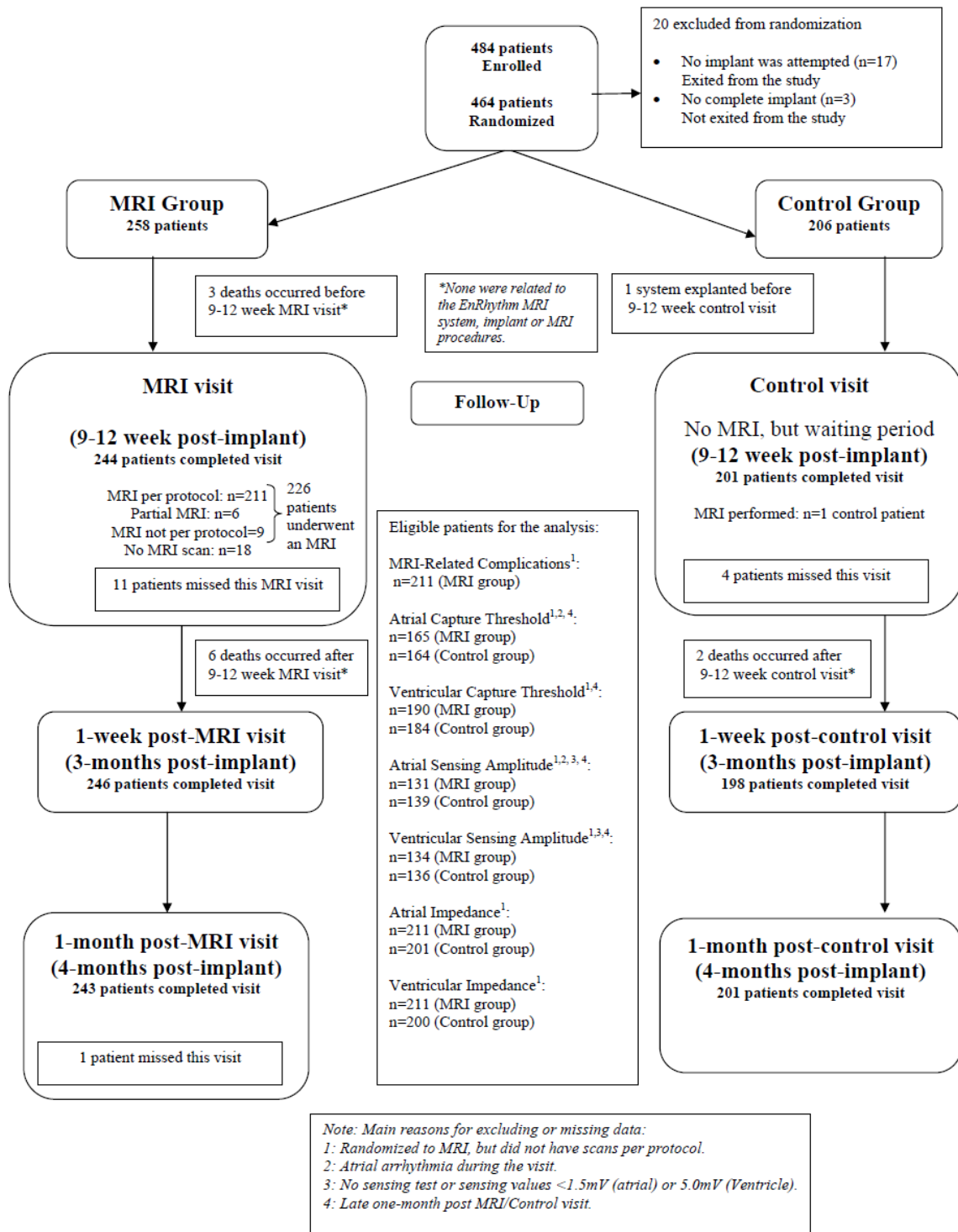
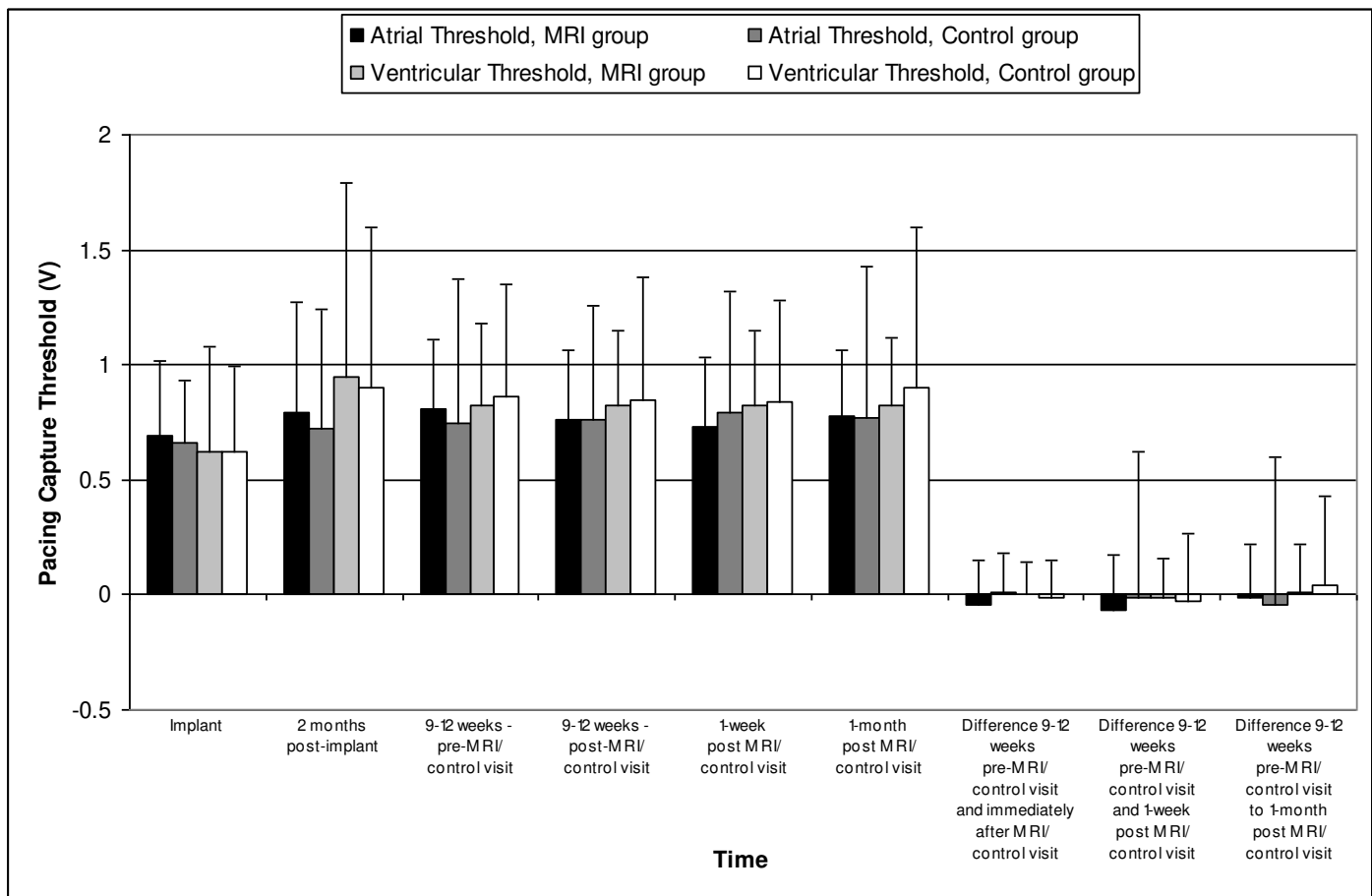
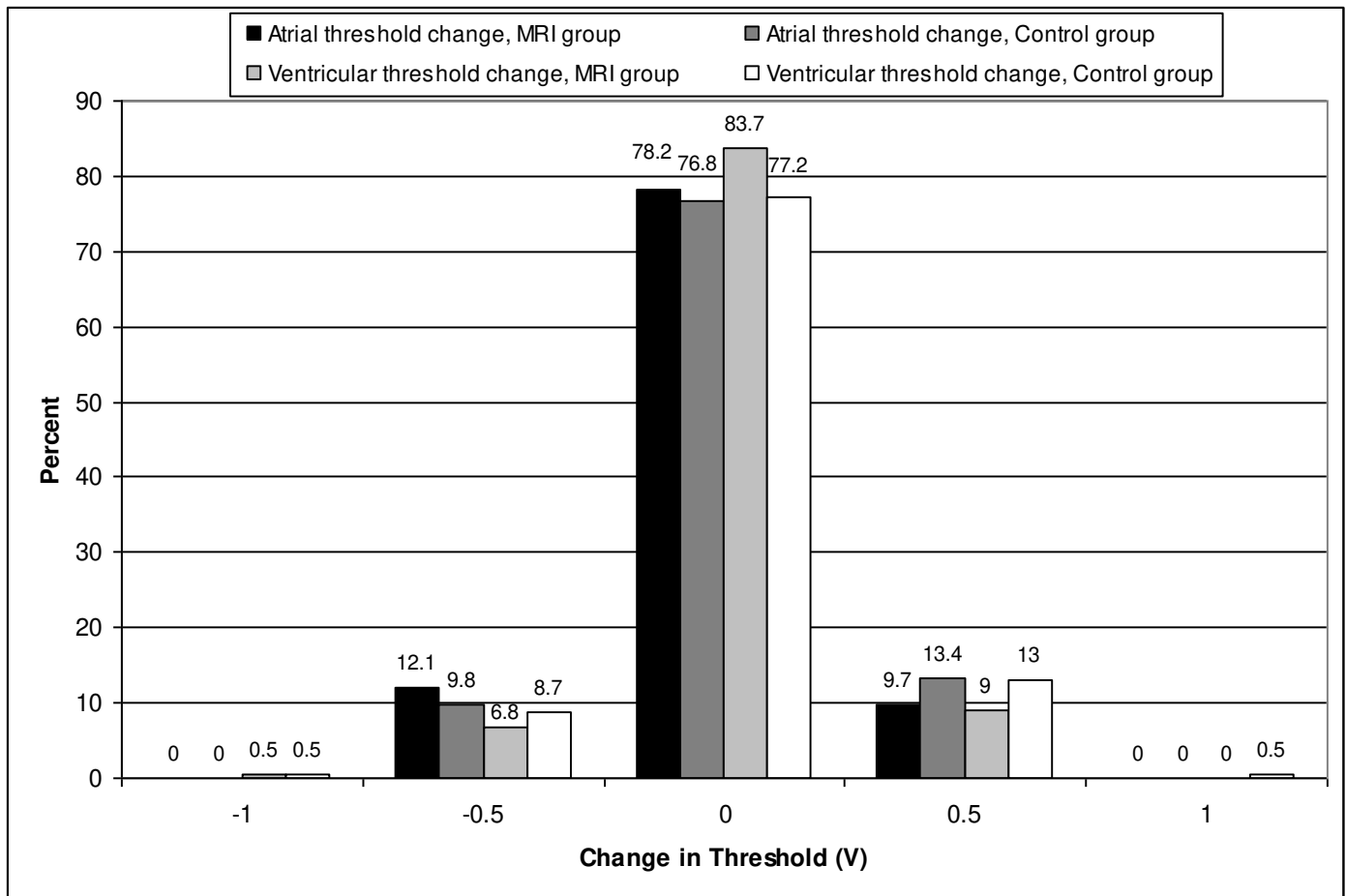


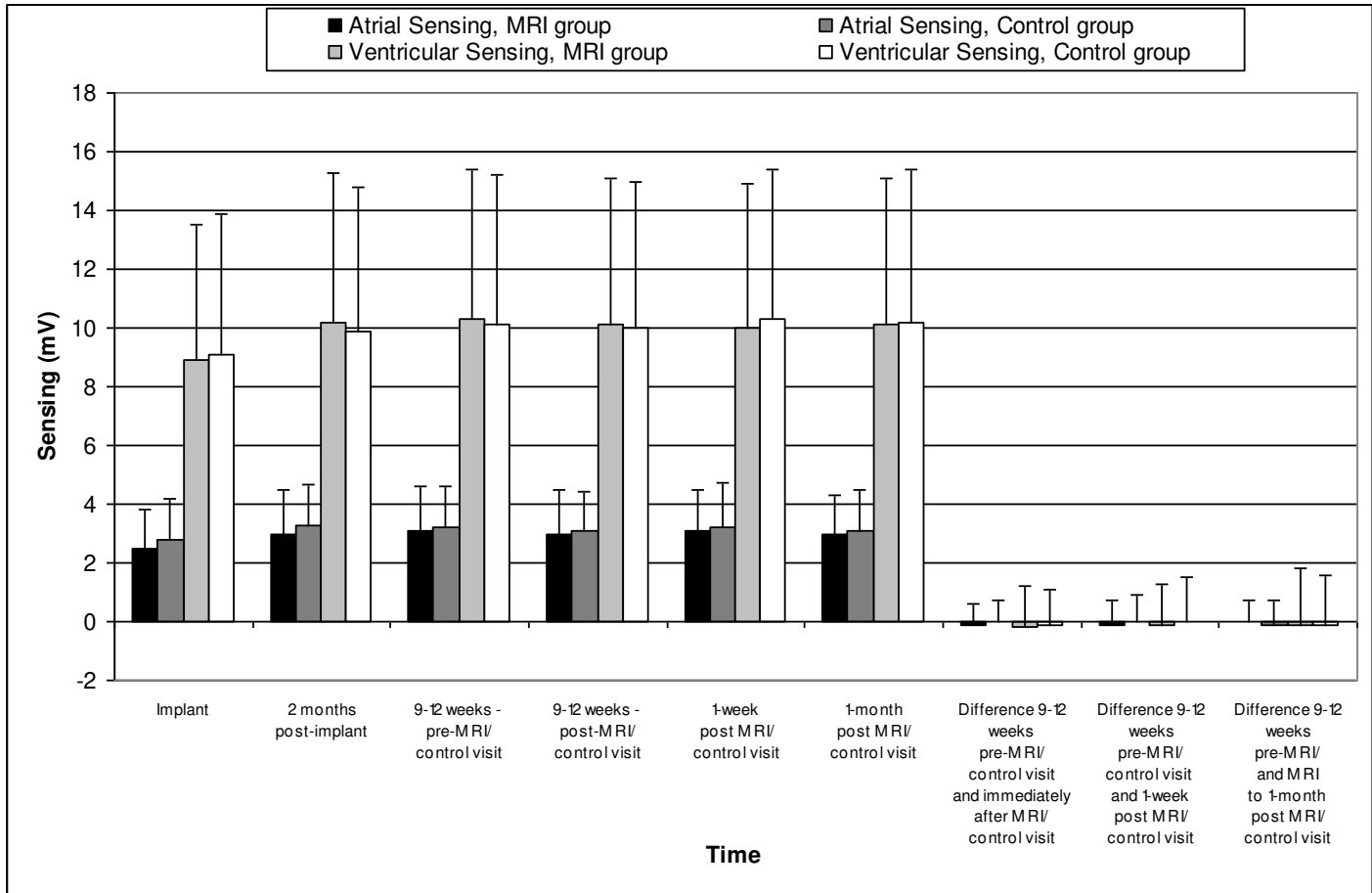
Figure 1: Flowchart of the study.



**Figure 2: Atrial and ventricular pacing capture thresholds at 0.5ms over time (mean + SD) and changes in pacing capture threshold within a group from directly before the MRI/control visit to immediately, 1-week and 1-month after MRI/control visit.**

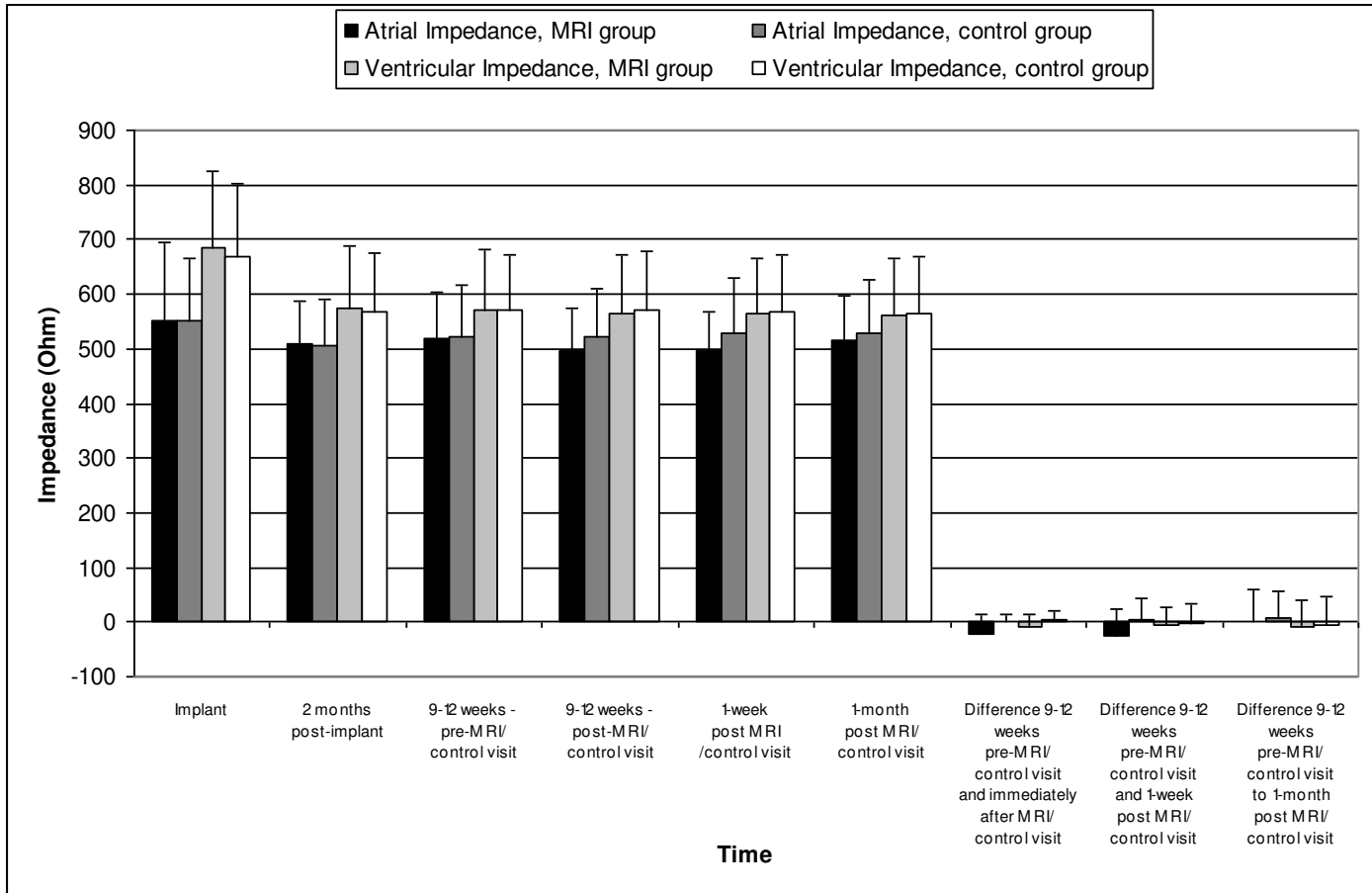


**Figure 3: Changes in atrial and ventricular pacing capture threshold at 0.5ms from 9-12 week visit (pre-MRI/pre-control visit) and 1-month post-MRI/post-control visit in each group.**



**Figure 4: Atrial and ventricular sensing (mean  $\pm$  SD) over time, including changes in sensing amplitudes within a group directly before the MRI/control visit to immediately, 1-week and 1-month after MRI/control visit.**





**Figure 5: Mean  $\pm$  SD atrial and ventricular impedance over time, including changes in lead impedance within a group directly before the MRI/control visit to immediately, 1-week and 1-month after MRI/control visit.**